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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 11

Application Number: 09/441,936
Filing Date: November 17, 1999
Appellant(s): BARDY ET AL.

Tony Piotrowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/3/02.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-5, 10, 13-14, 17-18, and 23.

Claims 6, 11-12, 15, and 19-22 are allowed.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: The grounds of rejection on appeal of claims 6, 11-12, 15, 19, 20, and 22 are no longer applicable.

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(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-6, 10-15, 17-20, 22, and 23 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8). The examiner agrees with the grouping of the claims made by the appellant.

(8) Claims Appealed

A substantially correct copy of appealed claims 1-6, 10-15, 17-20, 22, and 23 appears on page 15 of the Appendix to the appellant's brief. The minor errors are as follows: claim 3, line 2: "non-implanting" should be --non-implantable--, and claim 4, line 2: "non-implanting" should be --non-implantable--.

(9) Prior Art of Record

5,207,219	Adams et al.	05-1993
4,610,254	Morgan et al.	09-1986
5,509,925	Adams et al.	04-1996
6,292,692	Skelton et al.	09-2001
6,068,651	Brandell	05-2000
5,824,033	Ferrari	10-1998

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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 10, 13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) in view of Morgan et al. (4,610,254). Adams et al. shows an atrial defibrillator (30) comprising a housing (32); shock generator (76); and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation (Fig. 2). Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could also be implemented with an external defibrillator and associated defibrillator pads as is old and well known in the art (Col. 1, lines 28-32 and Col. 8, lines 33-43). Although Adams et al. does not teach that the shock generator (76) is operable to shock the patient via the pads in response to a shock command from an operator, attention is directed to Morgan et al. who teaches an external defibrillator comprising a portable non-implantable housing (12); a pair of defibrillator pads (30, 36); a shock generator (120, 122, 126) disposed in the housing and operable to shock the patient in response to a shock command from an operator (Col. 4, lines 46-48); an analyzer (388) disposed in the housing and operable to receive a cardiac signal from the patient to determine if the patient is

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experiencing fibrillation and to enable the shock generator (120, 122, 126) if the patient is experiencing fibrillation (Col. 13, line 56-Col. 14, lines 46). Morgan et al. teaches that the device is designed to be used interactively (i.e. the shock generator is enabled dependent on ECG analysis, but the operator must push the shock button to effect the defibrillation shock) so that a properly trained nonmedical operator can safely and effectively operate the device (Col. 1, lines 51-53). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the shock generator of the external atrial defibrillator of Adams et al. to make it operable in response to a shock command from an operator as Morgan et al. teaches in order to allow a properly trained nonmedical operator to safely and effectively operate the defibrillator device.

Regarding claim 2, Morgan et al. further shows a control device disposed in the housing, coupled to the shock generator (120, 122, 126) and operable to receive the shock command from the operator to activate the shock generator in response to the shock command. (Col. 9, lines 7-15).

With respect to claims 10 and 18, Adams et al. further shows the analyzer (62) is further operable to determine from the cardiac signal whether atrial fibrillation terminates after the shock generator shocks the patient (Col. 7, lines 44-60, Fig. 2, step 118).

Regarding claim 13, the previous rejection of claim 1 also applies to the method of claim 13.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) in view of Brandell (6,068,651). Adams et al. shows an atrial defibrillator (30) comprising a housing (32), a shock generator (76) and an analyzer (62) operable to receive a

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cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial fibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could also be implemented with an external defibrillator and associated defibrillator pads as is old and well known in the art (Col. 1, lines 28-32 and Col. 8, lines 33-43). Although Adams et al. does not teach of a safety device disposed in the housing and operable to prevent the patient from activating the shock generator, attention is directed to Brandell, which teaches a safety device to prevent the patient from activating the shock generator (Col. 7, lines 13-20, Col. 8, line 10-19). Brandell teaches that the safety device is used to prevent a patient from delivering an atrial defibrillation pulse at a time beyond when it is risky to deliver therapy without first administering anti-coagulants (Col. 2, lines 47-51). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the safety device of Brandell in the atrial defibrillator of Adams et al. in order to prevent a patient from delivering an atrial defibrillation pulse at a time beyond when it is risky to deliver therapy without first administering anti-coagulants.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) in view of Skelton et al. (6,292,692). Adams et al. shows an atrial defibrillator (30) comprising a housing (32); shock generator (76); and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could also be implemented with an external defibrillator and

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associated defibrillator pads as is old and well known in the art (Col. 1, lines 28-32 and Col. 8, lines 33-43). Although Adams et al. does not teach of a verification device disposed in the housing and operable to prevent an unauthorized person from activating the shock generator, attention is directed to Skelton et al., which teaches a verification device (44) (Col. 6, lines 44-47). Skelton et al. teaches that the verification device (44) prevents an untrained user from accessing some of the more advanced treatment modules of the external defibrillator such as manual defibrillation mode (Col. 4, line 65 - Col. 5, line 25). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the verification device of Skelton et al. in the external atrial defibrillator of Adams et al. in order to prevent an untrained user from accessing some of the more advanced treatment modules of the external defibrillator such as a manual defibrillation mode.

Claims 5, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) and Morgan et al. (4, 610,254) as applied to claims 1 and 13 above and further in view of Ferrari (5,824,033). Adams et al. and Morgan et al. are as explained before.

Although Adams et al. and Morgan et al. do not teach the defibrillator pads are capable of receiving the cardiac signal, electrode pads capable of both receiving ECG signals and delivering a defibrillation pulse are well known in the art as a means for limiting the number of electrodes and connections required (See Ferrari). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize the defibrillation/sense electrodes of Ferrari for the electrodes of the Adams et al. and Morgan et al. device since the use of combined sensing and shocking electrodes are well known in the art and would have the added benefit of eliminating additional electrodes and connections.

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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,509,925) in view of Adams et al. (5,207,219). Adams et al. ('925) shows receiving a cardiac signal from a patient; determining from the signal whether the patient is experiencing atrial fibrillation wherein the step of determining comprises determining the patient's heart rate, and determining that the patient is not in atrial fibrillation if the heart rate is outside a predetermined range (Col. 2, lines 32-35, Col. 8, line 33-Col. 9 line 50). Although Adams et al. ('925) shows the defibrillator (30) is implantable, Adams et al. ('219) teaches that the invention could also be implemented with an external defibrillator and associated defibrillator pads as is old and well known in the art (Col. 1, lines 28-32 and Col. 8, lines 33-43). The use of an external defibrillator and associated defibrillator pads compared to an implantable defibrillator offers the following advantages: it is non-invasive; does not require surgery and avoids the intrinsic risks and trauma associated with surgery; avoids the high cost of surgical intervention; can be used on any patient in an emergency; can be used on patients whose condition may not warrant the need for a chronic solution because they suffer from atrial fibrillation infrequently; and allows patients who are unfit for surgical intervention to receive atrial defibrillation shocks as needed. Therefore, it would have been a matter of obvious design choice to one with ordinary skill in the art at the time the invention was made employ the external atrial defibrillator of Adams et al ('219) for the implantable atrial defibrillator of Adams et al. ('925) based on these advantages of an external atrial defibrillator. Nevertheless, the appellant is not necessarily claiming that the defibrillator is an external defibrillator since the term "portable" can apply to an implantable defibrillator that can be carried regardless of whether it is carried prior to implantation, or carried by a patient while implanted within the patient.

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Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219). Adams et al. shows an atrial defibrillator (30) comprising a housing (32); shock generator (76); and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could also be implemented with an external defibrillator and associated defibrillator pads as is old and well known in the art (Col. 1, lines 28-32 and Col. 8, lines 33-43). Although Adams et al. fails to explicitly teach the shape of the defibrillation shock waveform, it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to use a multi-phasic defibrillation waveform since the choice of the particular type of defibrillation waveform used is a matter of treatment optimization where one with ordinary skill in the art aims to use the best waveform to suit the particular needs of the patient for the most effective therapy, and where the best waveform can be determined by routine experimentation. In any case, it is inherent that the shock generator (76) is “operable” to shock the patient with a multi-phasic waveform since the shock generator (76) is controlled by a charge delivery and energy control stage (72) that is part of the programmable microprocessor (62) (Col. 5, line 45-Col. 6, line 6); wherein the microprocessor could be programmed to deliver any or all of a mono-phasic, bi-phasic, or multi-phasic defibrillation waveform. By using the term “operable” the appellant is not necessarily claiming that the shock generator shocks the patient with a multi-phasic waveform, but simply that the generator is *capable* of operating in such a manner.

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(11) Response to Argument

In response to the argument for claims 1-2, appellant has argued that the Adams et al. ('219) reference is silent with regard to an operator performing the shock after the shock generator has been enabled in response to an analyzer unit determining that atrial defibrillation has occurred, the examiner concurs that this is true, thus a rejection under 35 USC § 103 (a) was made. The examiner maintains that the external atrial defibrillator with pads that Adams et al. teaches is modified by the teachings of Morgan et al. to direct an operator to press a shock button following rhythm analysis. Appellant further argues that the internal automatic shocking generation disclosed by Adams et al. is not a "functional equivalent" of an external system coupled with the inclusion of a shock button as disclosed by Morgan et al, the examiner respectfully disagrees. The examiner had asserted that the internal atrial defibrillator and the external atrial defibrillator with pads as taught by Adams et al. are functionally equivalent since both perform the function of atrial defibrillation. The Morgan et al. teaching is applied to the external atrial defibrillator of Adams et al. since it teaches the use of an interactive external defibrillator that enables a properly trained nonmedical operator to safely and effectively operate the defibrillator device. By informing the operator when to press the shock button, the Morgan et al. and Adams et al external defibrillator prevents a non-medical operator from applying a defibrillation pulse which may be deleterious and unsuccessful. The appellant also argues that Morgan et al. discloses a device for treatment of ventricular fibrillation, which is different from atrial fibrillation and the treatments are very different, the examiner agrees that Morgan et al. discloses treatment of ventricular fibrillation, but disagrees about the relevance of the difference between the treatments of atrial and ventricular fibrillation. The appellant has not pointed out

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how the treatments are “very different” or how this difference is relevant to the Morgan et al. teaching of an interactive external defibrillator which enables a properly trained nonmedical operator to safely and effectively operate the defibrillator. The fact that the intended use of the Morgan et al. external defibrillator is for treatment of ventricular fibrillation is irrelevant to the teaching of enabling a properly trained nonmedical operator to safely and effectively operate an external defibrillator regardless of whether the external defibrillator is for treatment of atrial or ventricular fibrillation.

In response to the arguments for claim 10, that the device determines whether atrial fibrillation has terminated after a shock has been applied is not disclosed or suggested by the combination of Adams et al. ('219) and Morgan et al., the examiner respectfully disagrees. Adams et al. does indeed show that the analyzer (62) determines whether atrial fibrillation has terminated after a shock has been applied (Col. 7, lines 44-60, Fig. 2, step 118). Attention is directed to the flow diagram of Fig. 2, which shows a closed loop of analysis and action. The diagram shows determining atrial fibrillation at 118, and delivery of a defibrillation shock at 122. Following delivery of a defibrillation shock at 122, the flow diagram returns to the top and continues down to step 118 where it again determines whether atrial fibrillation is occurring or not. Following this latest determination made after a shock has been applied, either another defibrillation shock is applied or the flow diagram returns to the top to continue analysis.

In response to the arguments for claim 13, that the combination of Adams et al. ('219) and Morgan et al. fails to disclose, suggest or motivate an artisan to provide a method for treating atrial fibrillation, the examiner respectfully disagrees. Adams et al. shows a method including receiving a cardiac signal from the patient and determining from the signal whether a patient is

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experiencing atrial fibrillation (steps 110-118 of Fig. 2) and shows shocking the patient if the patient is experiencing atrial fibrillation (steps 118, 120, 122 of Fig. 2) and teaches the use of a portable shock generator (Col. 8, lines 33-43). Morgan et al. teaches the step of receiving a shock command from an operator and shocking the patient in response to the shock command in order to allow a properly trained nonmedical operator to safely and effectively operate the defibrillator device. The issue of patient safety and effectiveness has always been a paramount motivation in the design of medical systems.

In response to the arguments for claim 18, that the claim would not have been obvious to one with ordinary skill in the art over the combination of Adams et al. ('219) and Morgan et al., the examiner respectfully disagrees. In addition to the method steps of claim 13 rejected by the combination of Adams et al. and Morgan et al., Adams et al. further shows the step of determining whether atrial fibrillation has terminated after a shock has been applied (Col. 7, lines 44-60, Fig. 2, step 118). Attention is directed to the flow diagram of Fig. 2, which shows a closed loop of analysis and action. The diagram shows determining atrial fibrillation at 118, and delivery of a defibrillation shock at 122. Following delivery of a defibrillation shock at 122, the flow diagram returns to the top and continues down to step 118 where again it determines whether atrial fibrillation is occurring or not. Following this latest determination made after a shock has been applied, either another defibrillation shock is applied or the flow diagram returns to the top to continue analysis.

In response to the arguments for claim 3, that Adams et al. ('219) discloses an internal automatic system for shocking a patient, where there is no initiation of a patient to have an operator shock a patient after an analyzer unit determined that atrial fibrillation has been

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experienced, the examiner agrees. However, claim 3 does not contain a recitation including "initiation of a patient to have an operator shock a patient". Absent this recitation, the examiner maintains that claim 3 is obvious over Adams et al. in view of Brandell as previously rejected under 35 U.S.C. 103(a).

In response to the arguments of claim 4, that the combination of Adams et al. ('219) and Skelton et al. fail to disclose, suggest or motivate an artisan such that the claim would be obvious over the combination of references, the examiner respectfully disagrees. Contrary to appellant's assertions that Adams et al. shows an automatic implantable device and Skelton et al. teaches a pass code for a manual device, the examiner respectfully points out that Adams et al. shows an implantable atrial defibrillator which may be modified to an external atrial defibrillator as Adams et al. teaches, while Skelton et al. teaches an external defibrillator that operates as an automatic external defibrillator by default, but prevents an operator from accessing a manual defibrillator mode via a pass code (Col. 5, lines 34-45). Appellant further argues that providing an external defibrillator is not a functional equivalent of an automatic internal defibrillator particularly when it is suggested in the Final Rejection that the functional equivalent is then modified to work in a manner inconsistent with the teaching of the reference. In response, the examiner maintains that the external atrial defibrillator of Adams et al. can indeed be combined with the teachings of Skelton et al. since Skelton et al. teaches the motivation of prohibiting untrained users from accessing a manual mode of an external defibrillator which already operates in an automatic mode by default. Appellant further argues that that there is no motivation to combine the teachings of Adams et al. and Skelton et al. and that the teaching allegedly suggested is actually coming from the appellant's claims, the examiner disagrees. As stated before, the external atrial

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defibrillator Adams et al. teaches can be combined with Skelton's teachings of an external defibrillator with a verification device since Skelton's verification device prevents untrained users from accessing the manual mode of an external defibrillator which already operates in an automatic mode upon start-up.

Appellant's arguments in favor of claims 5 and 14 state that they rely upon their dependence on claims 4, and 13 respectively. The examiner respectfully points out that claim 5 is actually dependent on claim 1 contrary to the statement in the argument that claim 5 is dependent on claim 4. Appellant further argues that the addition of Ferrari to the combination of Adams et al. and Morgan et al. still fails to disclose, suggest, or provide motivation for the claimed invention, the examiner disagrees. The Ferrari reference adds to the Adams et al. and Morgan et al. device the advantages of defibrillator pads which also sense an electric cardiac signal which are well known in the art and eliminate the need for additional electrodes and connections.

In response to the arguments for claim 17, that the combination of Adams et al. ('925) and Adams et al. ('219) fails to disclose that a patient is not in atrial fibrillation if the heart rate is outside of a predetermined range, the examiner respectfully disagrees. Adams et al. ('925) shows calculating the average heart interval (i.e. heart rate) and standard deviation of the heart interval and determining if these values are outside a predetermined range or within the predetermined range. If the average heart interval is less than 500 milliseconds and the standard deviation is greater than or equal to a predetermined standard deviation, the atrial fibrillation detector is enabled, while if the average heart interval is greater than 500 milliseconds and the standard deviation is less than or equal to a predetermined standard deviation, the atrial

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fibrillation detector is *not* enabled (Col. 8, line 33- Col 9, line 50, Fig. 3). The Appellant claims “determining from the signal whether the patient is experiencing atrial fibrillation *comprises* determining the patient’s heart rate and determining the patient is not in atrial fibrillation if the heart rate is outside of a predetermined range”. Adams teaches that the technique of enabling an atrial fibrillation detector only when the heart rate indicates that atrial fibrillation is likely, conserves battery power compared to atrial fibrillation detectors that continually monitor atrial fibrillation (Col. 2, lines 16-41). The Adams et al. (‘925) device does not *attempt* to detect atrial fibrillation when the heart range is outside the predetermined range because it is unlikely that it is occurring and uses valuable battery power, meaning in other words that the Adams et al. (‘925) device has already determined that atrial fibrillation is not occurring when the heart rate is outside this predetermined range. Appellant also argues that Adams et al. (‘925) shows probability of atrial fibrillation, which is distinguishable from a diagnosis of atrial fibrillation, the examiner respectfully disagrees. There is no recitation in the claim of “a diagnosis of atrial fibrillation” however; the claim does recite a “determination of atrial fibrillation”. Indeed, Adams et al. (‘925) does show determining from a cardiac signal whether a patient is experiencing atrial fibrillation using an atrial fibrillation detector (Col. 9, lines 34-42). Nevertheless, the examiner also wishes to point out that determinations are inherently based on probability, since few things are 100% decidedly clear.

In response to the arguments for claim 23, that Adams et al. (‘219) fails to disclose or suggest an operator shock a patient with a multi-phasic waveform, the examiner disagrees. There is no recitation in the claim that “an operator shock a patient with a multi-phasic waveform”, merely that the shock generator is operable to shock via a multi-phasic waveform.

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Appellant further argues that it would not be a functional equivalent or mere substitution to modify an internal defibrillator with an automatic shock generator to an external defibrillator with a multi-phasic waveform, the examiner disagrees. The examiner has not asserted that this is the case, rather, the examiner maintains that the internal atrial defibrillator is functionally equivalent to an external atrial defibrillator with associated defibrillator pads since both function to defibrillate a patient suffering from atrial fibrillation, and that it is the defibrillation waveform that is the design choice. The appellant also argues that Adams et al. is completely silent with regard to a multi-phasic waveform, the examiner agrees that Adams et al. fails to explicitly disclose the type of waveform that is applied as a defibrillation shock. By doing so, Adams et al. has not limited the device to any type of waveform, but rather left it open so that one could choose the most efficacious waveform from the known list of waveforms. The appellant argues that it is incorrect to assert that a multi-phasic waveform is suggested by Adams et al. because the appellant did not assert the criticality of such a waveform, the examiner disagrees. The examiner has not asserted that Adams et al. has suggested a multi-phasic waveform because the appellant did not set forth any criticality, rather, the examiner stated that it would have been an obvious matter of design choice based upon the fact that such waveforms are old and well known in the art and are within the context of external atrial defibrillators. (The examiner proffers Fain et al. (5,230,336) as an example that it is well known in the art to use a multi-phasic waveform with an external atrial defibrillator (Col. 1, lines 28-40, Col. 3, lines 7-20); and Baker Jr. et al. (5,974,339) as an additional example of a multi-phasic atrial defibrillator (Col. 4, lines 8-13)). Appellant further challenges the notion that the waveform applied is a matter of design choice given the seriousness of the application and the fact that a waveform to correct atrial fibrillation

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has been known in a number of instances to induce ventricular fibrillation, the examiner disagrees. Appellant has failed to point out the relevance of the waveform type to the induction of ventricular fibrillation or assert that any type of known safe waveform is more or less likely to induce ventricular fibrillation. For example, the appellant has not stated why a monophasic or bi-phasic defibrillation waveform applied at the proper time in the heart cycle would necessarily result in lethal ventricular fibrillation. Clearly the timing of the defibrillation shock waveform with regards to its occurrence in the heart cycle is most critical as recognized by Adams et al. (Col. 2, line 60-Col.3, line12), but the actual waveform used whether it is monophasic, bi-phasic or multi-phasic is a matter of design choice based upon individual patient parameters and routine experimentation. The appellant has not asserted why a multi-phasic waveform is critical to his invention and *only* his invention. Again, the appellant has failed to assert any criticality or advantage to using a multi-phasic defibrillation shock waveform over any other type of known safe waveform, and the examiner maintains that it would have been an obvious design choice to use a multi-phasic waveform barring any teaching in the Adams et al. reference against its use.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Krist Droe d

kld

August 23, 2002

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